

REMARKS

Claims 3-5 and 8-26 have been canceled.

Claims 1, 27 and 29 have been amended by further defining the substituents.

Support for R₅ and R₆ can be found in the Specification on page 1, lines 22-26.

Claim 27 and 28 have been amended to alter the claim dependency.

Claim 30 has been amended by deleting the phrase "or prophylaxis."

New claims 33-36 have been added. Support for claims 33-36 can be found in Example 85 on page 112 of the Specification and on page 8, lines 10-11 and line 31 to page 9 line 7.

No new matter has been added.

Claim Objections

The Examiner has objected to claim 28 for an incorrect recitation of dependency.

Applicants have amended claim 28, thereby overcoming the rejection.

Rejections Under 35 USC § 112, first paragraph

The Examiner has rejected claim 29 for lack of enablement stating that the Specification "does not reasonably provide enablement for compositions comprising any additional anti-HIV antiviral drugs whatsoever."

While Applicants strongly disagree with the Examiner's assessment and note that the claims are directed to the compounds themselves and not to the particular additional anti-HIV drugs, for the sole reason of expediting prosecution Applicants have

amended claim 29 to list the anti-HIV drugs listed in the Specification. Accordingly, Applicants respectfully request reconsideration and removal of the rejection.

The Examiner has rejected claims 30-32 for lack of enablement based upon the recitation of the phrase "or prophylaxis." Applicants have deleted this phrase, thereby overcoming the rejection.

Double Patenting

The Examiner has rejected claims 1-32 for non-statutory obviousness-type double patenting over claims 1-29 of US 6610714 ('714) stating that "claims 1-29 of '714 anticipate the claimed invention" as well as over claims 1-29 of US 6716850 ('850), again stating that "claims 1-29 of '850 anticipate the claimed invention." Applicants respectfully traverse.

Applicants first note that "...[T]he focus of any double patenting analysis necessarily is on the claims in the multiple patents or patent applications involved in the analysis." MPEP §804.

Applicants next note that the claims in the instant application have been amended and define R₂ as "pyrid-2-yl, substituted at the 5 position with the -(CHR₁₁)_p-E-(CHR₁₁)_q-R₁₀ moiety," define p and q as "0" (thereby causing CHR₁₁ to be absent), and define R₁₀ as "pyrid-3-yl, optionally substituted with halo or cyano." Thus, the structure of the right hand portion of the claimed molecule in the instant application versus that of '714, where R₂ is defined as an optionally substituted nitrogen-containing heterocycle with the nitrogen located at the 2 position relative to the (thio)urea bond, is very different and would be expected to have different properties. Consequently, based

on the disclosure of '714 and '850, the skilled artisan would not be motivated to generate the claimed compound and would have no reasonable expectation that it would work successfully.

The non-obviousness of the instant claims are further evidenced by the data presented in the attached Declaration by Dr. Christer Sahlberg. As stated in Dr. Sahlberg's Declaration, while there was some minimal expectation that the compounds of the instant application might have some of the activity of those of the '850 patent, as an example, the actual activity was found to be unpredictably and surprisingly improved. A comparison of the claimed compounds to Example 20 of '850, which Dr. Sahlberg considers to be the compound closest to the claimed compounds, indicates that the claimed compounds have between 4.4 and 29 times the potency of Example 20 of '850. As stated by Dr. Sahlberg, differences in HIV susceptibility of this order of magnitude are highly unexpected and have significant clinical application.

In view of the above, Applicants therefore respectfully request reconsideration and removal of the rejection.

The Examiner has also provisionally rejected claims 1-32 for non-statutory obviousness double patenting over claims 1-16 and 31-37 of copending Application No. 10/584,933. Applicants respectfully traverse.

Applicants note that the current claims have been amended. Comparing these amended claims to those in 10/584,933, the claims in 10/584,933 have the following seven (7) possibilities for R1:

(1) $-S(=O)_pRa$ where Ra is $-C_1-C_4$ alkyl, $-OR_x$, $-NR_xR_x$, $-NHNHNR_xR_x$, $-NHNHVR_x$, $-NHNHVR_x(=O)R_x$ and $-NR_xOH$

- (2) $-C(=O)-R_b$ where R_b is $-C_1-C_4$ alkyl, $-OR_x$, $-NR_xR_x$, $-NHN(R_x)R_x$, $-NH$
 C_1-C_4 - alkyl- $C(=O)R_x$ and $-NR_xR_c$
- (3) $-NR_xR_c$ where R_c is H, C_1-C_4 -alkyl, OR_x , $-NR_xR_x$, $-C(=O)R_d$, $-CN$,
 $-S(=O)_pR_x$ and
 where R_d is C_1-C_4 -alkyl, $-OR_x$, $-NR_xR_x$
 $-C_1-C_3$ -alkyl- $O-C_1-C_3$ alkyl- $C(=O)OR_x$;
- (4) $-C_1-C_3$ -alkyl- $COOR_x$
- (5) $-C_1-C_3$ -alkyl- OR_x
- (6) $-(O-C_1-C_3\text{-alkyl})_q-O-R_x$
- (7) a 5 or 6 membered aromatic ring having 1-3 hetero atoms

and where

p and q are independently selected from 1 or 2 and R_x is independently selected from H, C_1-C_4 alkyl, or acetyl; or a pair of R_x can together with the adjacent N atom form a pyrrolidine, piperidine, piperazine or morpholine ring.

Based on this fact, the skilled artisan would not have found the compounds claimed in the instant application to have been obvious variants of the 10/584,933 compounds. In other words, one of skill in the art would not have had a reasonable expectation that the instantly claimed compounds would have the same properties or efficacy as the compounds in 10/584,933. Consequently, Applicants respectfully request reconsideration and removal of the rejection.

Conclusion

In view of the above remarks, all the claims remaining in the case as amended, including newly added claims, are submitted as defining non-obvious, patentable subject matter. Reconsideration of the rejections and allowance of the claims are respectfully requested.

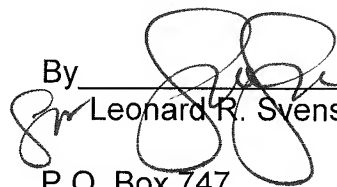
If the Examiner has any questions concerning this application, the Examiner is requested to contact Susan Gorman (Reg. No. 47,604) at 858-792-8855.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment(s) Declaration by Dr. Christer Salhberg